

### Subpart C—Application Procedures and Participation Agreement

#### § 425.200 Participation agreement with CMS.

(a) *General.* In order to participate in the Shared Savings Program, an ACO must enter into a participation agreement with CMS for a period of not less than the number of years specified in this section.

(b) *Agreement period.* (1) *For 2012.* For applications that are approved to participate in the Shared Savings Program for 2012, the start date for the participation agreement will be one of the following:

(i) April 1, 2012 (term of the participation agreement is 3 years and 9 months).

(ii) July 1, 2012 (term of the participation agreement is 3 years and 6 months).

(2) *For 2013 and through 2016.*

(i) The start date is January 1 of that year; and

(ii) The term of the participation agreement is 3 years unless all of the following conditions are met to extend the participation agreement by 6 months:

(A) The ACO entered an agreement period starting on January 1, 2016.

(B) The ACO elects to extend its agreement period until June 30, 2019.

(1) The ACO's election to extend its agreement period is made in the form and manner and according to the timeframe established by CMS; and

(2) An ACO executive who has the authority to legally bind the ACO must certify the election described in paragraph (b)(2)(ii)(B) of this section.

(3) *For 2017 and 2018.*

(i) The start date is January 1 of that year; and

(ii) The term of the participation agreement is 3 years, except as follows:

(A) For an ACO whose first agreement period in Track 1 began in 2014 or 2015, in which case the term of the ACO's initial agreement period under Track 1 (as described under § 425.604) may be extended, at the ACO's option, for an additional year for a total of 4 performance years if the conditions specified in paragraph (e) of this section are met.

(B) For an ACO whose agreement period started on January 1, 2018, the term of the participation agreement is extended by 12 months if both of the following conditions are met:

(1) The ACO elects to extend the participation agreement for a fourth performance year until December 31, 2021.

(2) The ACO's election to extend its agreement period is made in the form and manner and by a deadline established by CMS.

(4) *For 2019.* (i) The start date is January 1, 2019, and the term of the participation agreement is 3 years for ACOs whose first agreement period began in 2015 and who deferred renewal of their participation agreement under paragraph (e) of this section; or

(ii) The start date is July 1, 2019, and the term of the participation agreement is 5 years and 6 months.

(5) *For 2020 and subsequent years.* (i) The start date is January 1 of that year; and

(ii) The term of the participation agreement is 5 years.

(c) *Performance year.* The ACO's performance year under the participation agreement is the 12 month period beginning on January 1 of each year during the term of the participation agreement unless otherwise noted in its participation agreement, and except as follows:

(1) For an ACO with a start date of April 1, 2012, or July 1, 2012, the ACO's first performance year is defined as 21 months or 18 months, respectively.

(2) For an ACO that entered a first or second agreement period with a start date of January 1, 2016, and that elects to extend its agreement period by a 6-month period under paragraph (b)(2)(ii)(B) of this section, the ACO's fourth performance year is the 6-month period between January 1, 2019, and June 30, 2019.

(3) For an ACO that entered an agreement period with a start date of July 1, 2019, the ACO's first performance year of the agreement period is defined as the 6-month period between July 1, 2019, and December 31, 2019.

(d) *Submission of measures.* For each performance year of the agreement period, ACOs must submit measures in the form and manner required by CMS according to § 425.500(c) or § 425.510, as

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applicable, and as applicable according to §§ 425.608 and 425.609.

(e) *Optional fourth year.* (1) To qualify for a fourth performance year as described in paragraph (b)(3)(ii) of this section, the ACO must meet all of the following conditions:

(i) The ACO's first agreement period in the Shared Savings Program under Track 1 began in 2014 or 2015.

(ii) Is currently participating in its first agreement period under Track 1.

(iii) Has requested renewal of its participation agreement in accordance with § 425.224.

(iv) Has selected a two-sided model (as described under § 425.606 or § 425.610 of this part) in its renewal request.

(v) Has requested an extension of its current agreement period and a 1-year deferral of the start of its second agreement period in a form and manner specified by CMS.

(vi) CMS approves the ACO's renewal, extension, and deferral requests.

(2) An ACO that is approved for renewal, extension, and deferral that terminates its participation agreement before the start of the first performance year of the second agreement period is—

(i) Considered to have terminated its participation agreement for the second agreement period under § 425.220; and

(ii) Not eligible to participate in the Shared Savings Program again until after the date on which the term of that second agreement period would have expired if the ACO had not terminated its participation, consistent with § 425.222.

[76 FR 67973, Nov. 2, 2011, as amended at 80 FR 32837, June 9, 2015; 81 FR 38013, June 10, 2016; 83 FR 60092, Nov. 23, 2018; 83 FR 68063, Dec. 31, 2018; 85 FR 27625, May 8, 2020; 85 FR 85038, Dec. 28, 2020]

### § 425.202 Application procedures.

(a) *General rules.* (1) In order to obtain a determination regarding whether it meets the requirements to participate in the Shared Savings Program, a prospective ACO must submit a complete application in the form and manner required by CMS by the deadline established by CMS.

(2) An ACO executive who has the authority to legally bind the ACO must certify to the best of his or her knowl-

edge, information, and belief that the information contained in the application is accurate, complete, and truthful.

(3) An ACO that seeks to participate in the Shared Savings Program and was newly formed after March 23, 2010, as defined in the Antitrust Policy Statement, must agree that CMS can share a copy of their application with the Antitrust Agencies.

(b) *Condensed application form.* For determining eligibility for agreement periods beginning before July 1, 2019: (1) PGP demonstration sites applying to participate in the Shared Savings Program will have an opportunity to complete a condensed application form.

(2) A Pioneer ACO may use a condensed application form to apply for participation in the Shared Savings Program if it satisfies all of the following criteria:

(i) The applicant is the same legal entity as the Pioneer ACO.

(ii) The applicant's ACO participant list does not contain any ACO participant TINs that did not appear on the "Confirmed Annual TIN/NPI List" (as defined in the Pioneer ACO Model Innovation Agreement with CMS) for the applicant ACO's last full performance year in the Pioneer ACO Model.

(iii) The applicant is not applying to participate in the one-sided model.

(c) *Application review.* CMS reviews applications in accordance with § 425.206.

[76 FR 67973, Nov. 2, 2011, as amended at 80 FR 32837, June 9, 2015; 83 FR 68063, Dec. 31, 2018]

### § 425.204 Content of the application.

(a) *Accountability for beneficiaries.* As part of its application and participation agreement, the ACO must certify that the ACO, its ACO participants, and its ACO providers/suppliers have agreed to become accountable for the quality, cost, and overall care of the Medicare fee-for-service beneficiaries assigned to the ACO.

(b) *Prior participation.* Upon request by CMS during the application cycle, the ACO must submit information regarding prior participation in the Medicare Shared Savings Program by the ACO, its ACO participants, or its ACO providers/suppliers, including such

information as may be necessary for CMS to determine whether to approve an ACO's application in accordance with § 425.224(b).

(2) The ACO must specify whether the related participation agreement is currently active or has been terminated. If it has been terminated, the ACO must specify whether the termination was voluntary or involuntary.

(3) If the ACO, ACO participant, or ACO provider/supplier was previously terminated from the Shared Savings Program, the ACO must identify the cause of termination and what safeguards are now in place to enable the ACO, ACO participant, or ACO provider/supplier to participate in the program for the full term of the participation agreement.

(c) *Eligibility.* (1) As part of its application, an ACO must certify that the ACO satisfies the requirements set forth in this part. Upon request, the ACO must submit the following supporting materials to demonstrate that it satisfies the requirements set forth in this part:

(i) Documents (for example, ACO participant agreements, agreements with ACO providers/suppliers, employment contracts, and operating policies) sufficient to describe the ACO participants' and ACO providers'/suppliers' rights and obligations in and representation by the ACO, and how the opportunity to receive shared savings or other financial arrangements will encourage ACO participants and ACO providers/suppliers to adhere to the quality assurance and improvement program and evidence-based clinical guidelines.

(ii) A description, or documents sufficient to describe, how the ACO will implement the required processes and patient-centeredness criteria under § 425.112, including descriptions of the remedial processes and penalties (including the potential for expulsion) that will apply if an ACO participant or an ACO provider/supplier fails to comply with and implement these processes.

(iii) Materials documenting the ACO's organization and management structure, including an organizational chart, a list of committees (including names of committee members) and their structures, and job descriptions

for senior administrative and clinical leaders specifically noted in § 425.108 and § 425.112(a)(2).

(iv) Evidence that the governing body—

(A) Is an identifiable body;

(B) Represents a mechanism for shared governance for ACO participants;

(C) Is composed of representatives of its ACO participants; and

(D) Is at least 75 percent controlled by its ACO participants.

(v) Evidence that the governing body includes a Medicare beneficiary representative(s) served by the ACO who does not have a conflict of interest with the ACO, and who has no immediate family member with conflict of interest with the ACO.

(vi) A copy of the ACO's compliance plan or documentation describing the plan that will be put in place at the time the participation agreement with CMS becomes effective.

(2) Upon request, the ACO must provide copies of all documents effectuating the ACO's formation and operation, including, without limitation the following:

(i) Charters.

(ii) By-laws.

(iii) Articles of incorporation.

(iv) Partnership agreement.

(v) Joint venture agreement.

(vi) Management or asset purchase agreements.

(vii) Financial statements and records.

(viii) Resumes and other documentation required for leaders of the ACO.

(3) If an ACO requests an exception to the governing body requirement in § 425.106(c)(2) or (c)(3), the ACO must describe—

(i) Why it seeks to differ from the requirement; and

(ii) If seeking an exception to § 425.106(c)(2), how the ACO will provide meaningful representation in ACO governance by Medicare beneficiaries.

(iii) If seeking an exception to the requirement at § 425.106(c)(3), for agreement periods beginning before January 1, 2024, why the ACO is unable to meet the requirement and how it will involve ACO participants in innovative ways in ACO governance.

(4)(i) An ACO must certify that it is recognized as a legal entity in the State, Federal or Tribal area in which it was established and that it is authorized to conduct business in each State or Tribal area in which it operates.

(ii) An ACO formed among two or more ACO participants must provide evidence in its application that it is a legal entity separate from any of the ACO participants.

(5) The ACO must provide CMS with such information regarding its ACO participants and its ACO providers/suppliers participating in the program as is necessary to implement the program.

(i) The ACO must submit a list of all ACO participants and ACO providers/suppliers in accordance with § 425.118.

(ii) ACOs must also submit any other specific identifying information as required by CMS in the application process.

(iii) The ACO must certify the accuracy of this information.

(6) Upon request by CMS during the application cycle or at any point during an agreement period, the ACO must submit documents demonstrating that its ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities are required to comply with the requirements of the Shared Savings Program. Upon such a request, the evidence to be submitted must include, without limitation, sample or form agreements and, in the case of ACO participant agreements, the first and signature page(s) of each executed ACO participant agreement. CMS may request all pages of an executed ACO participant agreement to confirm that it conforms to the sample form agreement submitted by the ACO. The ACO must certify that all of its ACO participant agreements comply with the requirements of this part.

(d) *Distribution of savings.* As part of its application to participate in the Shared Savings Program, an ACO must certify it has a mechanism and plan to receive and use payments for shared savings, including criteria for distributing shared savings among its ACO participants and ACO providers/suppliers.

(e) *Selection of track and option for interim payment calculation.* (1) As part of its application, an ACO must specify the Track for which it is applying (as described in § 425.600).

(2)(i) An ACO applying to participate in the program with a start date of April 1, 2012 or July 1, 2012, has the option of requesting an interim payment calculation based on the financial performance for its first 12 months of program participation and quality performance for CY 2012.

(ii) An ACO must request interim payment calculation as part of its application to participate in the Shared Savings Program.

(f) *Assurance of ability to repay.* (1) An ACO must have the ability to repay all shared losses for which it may be liable under a two-sided model.

(2) An ACO that will participate in a two-sided model must establish one or more of the following repayment mechanisms in an amount and by a deadline specified by CMS in accordance with this section:

(i) An escrow account with an insured institution.

(ii) A surety bond from a company included on the U.S. Department of Treasury's List of Certified Companies.

(iii) A line of credit at an insured institution (as evidenced by a letter of credit that the Medicare program can draw upon).

(3) An ACO that will participate under a two-sided model of the Shared Savings Program must submit for CMS approval documentation that it is capable of repaying shared losses that it may incur during its agreement period, including details supporting the adequacy of the repayment mechanism.

(i) An ACO participating in Track 2 must demonstrate the adequacy of its repayment mechanism prior to any change in the terms and type of the repayment mechanism, and at such other times as requested by CMS.

(ii) An ACO entering an agreement period in Levels C, D, or E of the BASIC track or the ENHANCED track must demonstrate the adequacy of its repayment mechanism prior to the start of its agreement period, prior to any change in the terms and type of the repayment mechanism, and at such other times as requested by CMS.

(iii) An ACO entering an agreement period in Level A or Level B of the BASIC track must demonstrate the adequacy of its repayment mechanism prior to the start of any performance year in which it either elects to participate in, or is automatically transitioned to, a two-sided model, Level C, Level D, or Level E of the BASIC track, prior to any change in the terms and type of the repayment mechanism, and at such other times as requested by CMS.

(iv) An ACO that has submitted a request to renew its participation agreement must submit as part of the renewal request documentation demonstrating the adequacy of the repayment mechanism that could be used to repay any shared losses incurred for performance years in the next agreement period. The repayment mechanism applicable to the new agreement period may be the same repayment mechanism currently used by the ACO, provided that the ACO submits documentation establishing that the duration of the existing repayment mechanism has been revised to comply with paragraph (f)(6)(ii) of this section, and the amount of the repayment mechanism complies with paragraph (f)(4) of this section.

(v) As part of its application, a re-entering ACO must submit documentation demonstrating the adequacy of the repayment mechanism that could be used to repay any shared losses incurred for performance years in the next agreement period. The repayment mechanism applicable to the new agreement period may be the same repayment mechanism currently used by the re-entering ACO, provided that the ACO is the same legal entity as an ACO that previously participated in the program, and the ACO submits documentation establishing that the duration of the existing repayment mechanism has been revised to comply with paragraph (f)(6)(ii) of this section and the amount of the repayment mechanism complies with paragraph (f)(4) of this section.

(4) CMS calculates the amount of the repayment mechanism as follows:

(i) For a Track 2 ACO, the repayment mechanism amount must be equal to at least 1 percent of the total per capita

Medicare Parts A and B fee-for-service expenditures for the ACO's assigned beneficiaries, based on expenditures used to calculate the benchmark for the applicable agreement period, as estimated by CMS at the time of application.

(ii) For a BASIC track or ENHANCED track ACO, the repayment mechanism amount must be equal to the lesser of the following:

(A) One-half percent of the total per capita Medicare Parts A and B fee-for-service expenditures for the ACO's assigned beneficiaries, based on expenditures and the number of assigned beneficiaries for the most recent calendar year for which 12 months of data are available.

(B) One percent of the total Medicare Parts A and B fee-for-service revenue of its ACO participants, based on revenue for the most recent calendar year for which 12 months of data are available, and based on the ACO's number of assigned beneficiaries for the most recent calendar year for which 12 months of data are available.

(iii) CMS recalculates the ACO's repayment mechanism amount for the second and each subsequent performance year in the agreement period in accordance with paragraph (f)(4)(ii) of this section based on the certified ACO participant list for the relevant performance year, except that the number of assigned beneficiaries used in the calculations is the number of beneficiaries assigned to the ACO at the beginning of the relevant performance year under § 425.400(a)(2)(i) (for ACOs under preliminary prospective assignment with retrospective reconciliation) or § 425.400(a)(3)(i) (for ACOs under prospective assignment).

(A) If the recalculated repayment mechanism amount exceeds the existing repayment mechanism amount by at least \$1,000,000, CMS notifies the ACO in writing that the amount of its repayment mechanism must be increased to the recalculated repayment mechanism amount.

(B) Within 90 days after receipt of such written notice from CMS, the ACO must submit for CMS approval documentation that the amount of its

repayment mechanism has been increased to the amount specified by CMS.

(iv)(A) In the case of an ACO that has submitted a request to enter a new participation agreement for an agreement period starting on or after January 1, 2022 and is a renewing ACO or a re-entering ACO that is the same legal entity as an ACO that previously participated in the program: If the ACO wishes to use its existing repayment mechanism to establish its ability to repay any shared losses incurred for performance years in the new agreement period, the amount of the repayment mechanism must be equal to at least the amount calculated by CMS in accordance with paragraph (f)(4)(ii) of this section.

(B) Under the following circumstances, an ACO that renewed its participation agreement for an agreement period beginning on July 1, 2019, or January 1, 2020, may elect to decrease the amount of its repayment mechanism.

(1) The ACO elected to continue to use its existing repayment mechanism for the agreement period beginning on July 1, 2019, or January 1, 2020, and the amount of that repayment mechanism was greater than the repayment mechanism amount estimated at the time of renewal application according to paragraph (f)(4)(ii) of this section.

(2) The repayment mechanism amount for performance year 2021, as recalculated pursuant to paragraph (f)(4)(iii) of this section, is less than the existing repayment mechanism amount.

(3) CMS will notify the ACO in writing if the ACO may elect to decrease the amount of its repayment mechanism pursuant to this paragraph (f)(4)(iv)(B). The ACO must submit such election, together with revised repayment mechanism documentation, in a form and manner and by a deadline specified by CMS. CMS will review the revised repayment mechanism documentation and may reject the election if the repayment mechanism documentation does not comply with the requirements of this paragraph (f).

(v)(A) An ACO that established a repayment mechanism to support its participation in a two-sided model begin-

ning on July 1, 2019, January 1, 2020, or January 1, 2021, may elect to decrease the amount of its repayment mechanism if the repayment mechanism amount for performance year 2022, as recalculated pursuant to paragraph (f)(4)(iii) of this section, is less than the existing repayment mechanism amount.

(B) CMS will notify the ACO in writing if the ACO may elect to decrease the amount of its repayment mechanism pursuant to this paragraph (f)(4)(v). The ACO must submit such election, and revised repayment mechanism documentation, in a form and manner and by a deadline specified by CMS. CMS will review the revised repayment mechanism documentation and may reject the election if the repayment mechanism documentation does not comply with the requirements of this paragraph (f).

(5) After the repayment mechanism has been used to repay any portion of shared losses owed to CMS, the ACO must replenish the amount of funds available through the repayment mechanism within 90 days. The resulting amount available through the repayment mechanism must be at least the amount specified by CMS in accordance with paragraph (f)(4) of this section.

(6) The repayment mechanism must be in effect for the duration of the ACO's participation under a two-sided model plus 12 months following the conclusion of the agreement period, except as otherwise specified in this section.

(i) For an ACO that is establishing a new repayment mechanism to meet this requirement, the repayment mechanism must satisfy one of the following criteria:

(A) The repayment mechanism covers the entire duration of the ACO's participation under a two-sided risk model plus 12 months following the conclusion of the agreement period.

(B) The repayment mechanism covers a term of at least the first two performance years in which the ACO is participating under a two-sided model and provides for automatic, annual 12-month extensions of the repayment mechanism such that the repayment mechanism will eventually remain in